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February 12, 2004

Via Express Mail and Email

Mr. Donald S. Clark
Office of the Secretary
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Comments Regarding Hearings on Health Care and Competition Law and Policy

Dear Mr. Clark:

On behalf of the Section of Antitrust Law of the American Bar Association ("the Section"), I am pleased to submit the enclosed comments regarding Hearings on Health Care and Competition Law and Policy to the Federal Trade Commission.

Please note that these views are being presented only on behalf of the Section of Antitrust Law and have not been approved by the House of Delegates or the Board of Governors of the American Bar Association and should not be construed as representing the position of the American Bar Association.

If you have any questions after reviewing this report, we would be happy to provide further comments.

Sincerely,

Kevin E. Grady
Chair, Section of Antitrust Law

Enclosure

cc: Hon. Timothy J. Muris
Hon. R. Hewitt Pate
Mr. Jeffrey W. Brennan
Mr. David Hyman
Mr. David Kelly

COMMENTS ON THE PUBLIC HEARINGS ON HEALTH CARE AND COMPETITION LAW AND POLICY

Section of Antitrust Law
American Bar Association
December 18, 2003

I. INTRODUCTION

The Section of Antitrust Law of the American Bar Association (the "Section") submits these comments on the Public Hearings on Health Care and Competition Law and Policy, conducted by the Federal Trade Commission (the "Commission") and the Department of Justice ("DOJ") (together, the "Agencies") from February through October, 2003. These views are presented only on behalf of the Section. They have not been approved by the House of Delegates or the Board of Governors of the American Bar Association ("ABA"), and should not be construed as representing the position of the ABA.

The Section applauds the Commission and the DOJ for closely examining antitrust enforcement in health care in light of market trends and developments in the industry; providing a forum for the expression of views by all segments of the industry; and providing a context within which to consider various types of specific conduct as well as organizational and structural change that occur in health care and that have competitive significance.

The Section believes these hearings lay the groundwork for the achievement of the Agencies' articulated goals, including to improve the conceptual foundation of competition policy, to select the right tools to form and execute that policy, to achieve greater transparency in the Agencies' law enforcement policies in health care, to improve the dissemination of service-related information to consumers, to guard against the market dislocations that occur as a result of excessive market power in the hands of market participants (*e.g.,* providers or payors), and, importantly, to augment the use of empirical evidence in evaluating the competitive implications of various practices or changes in the health care industry.

The Section appreciates the Agencies' consideration of various issues the Section, among others, has previously indicated merit attention, including those identified in the Section's October 2002 "Comments Regarding the Federal Trade Commission's Workshop on Health Care

and Competition Law and Policy" ("Section's Workshop Comments"). Those issues include, for example, clinical integration, quality of care, group purchasing organizations, virtual mergers, monopoly conduct by providers, and monopsony power possessed by health plans or generated by health plan mergers. The hearings focused on each of these issues at some length, and the Agencies are to be commended for that.

The Agencies succeeded in identifying a variety of specific and current industry trends and novel arrangements in health care that merit consideration as fundamental economic factors in the industry as well as in specific competitive situations. These include, for example, the increased number of health plan consolidations and mergers; the need to distinguish bona fide joint venture activity from activity only disguised to shield anticompetitive coordination; increased competition for acute care hospitals from specialty hospitals; the significance of emerging quality measures and the ways competition may be affected; changes in managed care contracting practices, including, for example, the use of "all products," "no tiering," and all facilities clauses as well as the shift in the balance of negotiating strength from health plans to providers in some markets (and the reverse in others) during the past several years; upward pressure on commercial reimbursement rates due to reduced Medicare reimbursement as well as increased costs; the response of managed care to consumer demands for increased choice, and the decreasing "management" and cost control of health care emanating from the payor level.

The sessions also identified areas where market imperfections may require changes in how one employs the competitive model. Participants identified, for example, the difficulty courts have in dealing with market imperfections, inadequate information flow (particularly to consumers), the failure to achieve the full efficiencies expected from industry consolidation and the difficulty the market has in setting cost-quality tradeoffs. These observations present clear

challenges for antitrust enforcement and competition policy in terms of whether and how to deal with market imperfections or the influence of regulatory requirements on pricing and outcomes in the health care industry.

The Section welcomes the opportunity to submit these comments on issues relating to competition policy and antitrust enforcement that were raised in the hearings. The Section hopes these views will be helpful to the Agencies in their consideration of next steps to be implemented in the aftermath of the hearings. In appropriate instances, those "next steps" may include the further development or supplementation of the Statements of Antitrust Enforcement Policy in Health Care ("Policy Statements") in specific areas. The Section would be pleased to work with the Agencies and to offer additional views as appropriate as the Agencies consider the further development of competition policy in the health care industry.

II. MORE GUIDANCE AND EMPIRICAL ANALYSIS FROM THE AGENCIES

A. General Advice from the Agencies

1. More Transparency in Analysis

There was a thoughtful discussion at the hearings on Agency advice. The panelists explored the advantages and disadvantages of seeking prospective guidance from the Commission, DOJ and State attorneys general. The hearings also explored the costs and benefits of issuing guidelines for the health care industry.

The Section believes that the Policy Statements, informal advisory opinions, speeches by Agency officials, and these hearings are particularly useful to the private bar and to health care providers and others attempting to comply with the antitrust laws. The Section fully agrees with the general consensus expressed at the hearings that advisory opinions are a major source of antitrust advice to clients in the health care industry, and the private bar frequently cites them.

The Section also agrees that the Policy Statements have provided helpful guidance. Although "resource intens[ive]," they have been very important in terms of educating lawyers and the public about antitrust analysis in the health care industry. The Section believes that it is important, however, to update and extend the Policy Statements to assure their usefulness and relevancy over time.

The Section fully supports additional guidance from the Agencies, particularly in areas where a specific need for advice has been identified. Since the Agencies have no control over the issues that are submitted to them for informal advice, the Section encourages the Agencies to utilize other avenues, such as speeches or revisions or expansion of the Policy Statements on these issues, to provide additional guidance. Reports on hearings such as these are also helpful in providing a general overview of recent developments and trends in the health care industry and can be used to explain the Agencies' enforcement positions and legal analysis of important issues.

There was some criticism during the hearings about lack of transparency by the Agencies with respect to their enforcement actions, particularly on closed transactions and investigations in which no action was taken. Subject to confidentiality restrictions, the Section encourages the Agencies to provide greater transparency in their enforcement decisions. The Section believes that it would be helpful if more information were provided to the public when a request for informal advice is withdrawn due to substantive reasons or an Agency investigation is closed.[1]

The Section also requests that the speeches by Agency officials be regularly published on the Agency's website, particularly when such speeches are given to a limited or closed audience. It would also prove useful if the Agencies could periodically conduct an assessment of the

[1] The Statement of the Federal Trade Commission Concerning Royal Caribbean Cruises, Ltd., FTC File No. 021 0041 (Oct. 4, 2002) is one example of this.

effectiveness of the indices and search engines on their respective websites. The Section would also encourage the States to put their procedures for obtaining informal advice and their informal advisory opinions on their websites and on commonly used websites like the National Association of Attorneys General website or in the antitrust reporters.

2. Bibliography from the Hearings

The hearings brought together a wide array of academics, practitioners, and industry specialists with extensive background on the health care industry. A number of these speakers provided references to both recent published as well as unpublished literature on a number of key topics, including empirical reviews of mergers, surveys of contracting practices, cost-shifting, use of new payor methodologies for encouraging use of lower cost providers, pricing studies, and academic studies on the effect of non-profit or for-profit status on the incentives of hospitals. As a result, the hearings have provided an opportunity to collect in one place an extensive bibliography of such materials as a resource for practitioners as well as academics (including indicators of which areas may require substantial additional research). We would encourage the Agencies to collect the articles and papers already identified, and potentially to expand the bibliography to include additional materials. The Section would be willing to assist in the process of augmenting the bibliography or in facilitating its development.

B. Provider Issues

1. Single Specialty Hospitals

There was substantial testimony at the hearings with respect to single specialty hospitals and the competitive responses of some hospitals. The panelists explained that the reasons for the growth in single specialty hospitals include the following: (1) revenue opportunities less constrained by managed care and government program limits on reimbursement for professional

services; (2) disproportionately higher Medicare reimbursement rates for certain procedures (including cardiac and orthopedics); (3) a squeeze on physician income; (4) physicians wanting greater input and control; (5) the growth of entrepreneurial firms that have spurred this development; and (6) growth in outpatient procedures.

The panelists also noted the competitive responses of some community hospitals have been: (1) a preemptive strike by establishing their own specialty hospitals; (2) joint ventures with local physicians; (3) taking a stance against specialty hospitals and fighting physicians through forms of economic credentialing (denying privileges to physicians with an economic stake in a competitor) that may potentially raise competitive issues; and (4) discouraging health plans from contracting with competing physicians.

Another issue that was discussed was that physicians with an ownership interest in a specialty hospital have a conflict of interest in referring patients to that facility.[2] This can result in increased utilization (supply-induced demand), duplication of facilities and increased overall health care costs. "Full-service" hospitals reportedly have been hurt by these dynamics through patient dumping at full service hospitals, revenue losses that threaten the hospitals' community missions, staffing shortages, threats to emergency room call coverage, abuse of the peer review process to discipline these physicians, and deteriorating board and medical staff relations. Some fear that the effect on many hospitals is likely to be diminishing services, poorer quality or increased costs for the remaining services, thereby causing increased costs to payors, employers and consumers. Because cross-subsidization from more profitable services is a way of funding uncompensated care, the financial viability of some hospitals may be threatened by single

[2] In this regard, we note that the recently passed Medicare Reform Bill imposes an 18-month moratorium on the availability of the whole-hospital exemption from the "Stark" anti-referral laws for specialty hospitals. The bill also requires the Department of Health and Human Services to study patterns of physician referrals to specialty hospitals in which they have an ownership interest. The results of the

specialty hospitals to the extent that revenues from the more profitable services are reduced or eliminated. At the same time, antitrust principles do not normally countenance otherwise anticompetitive practices on grounds of necessity to satisfy societal needs that are not met by the market. Careful analysis of the specific practices engaged in by hospitals, as well as the market context, therefore is important.

The Section believes that this is an area where the Agencies could provide some additional analysis or guidelines with respect to the competitive issues presented by both the formation of a single specialty hospital by physicians and the competitive responses of community hospitals, especially the impact that the existence of market power of the community hospital or the investing physicians could have on the analysis. The Agencies have provided helpful guidance to hospital joint ventures involving high-technology or other expensive health care equipment in Statement 2 of the Policy Statements which could be expanded to address, or could provide the basis for addressing, the issues presented by the formation of a single specialty hospital by competing physicians.

Although many of the competitive responses of community hospitals to single specialty hospitals or other facilities owned by physicians raise traditional issues of tying and exclusive contracts, other issues, such as economic credentialing and the need for cross-subsidization to fund uncompensated or underfunded required care are more unique to the health care industry. None of these issues is addressed in the Policy Statements or in any other guidance recently provided by the Agencies. The Section believes that additional guidance would be particularly helpful and timely and would encourage the Agencies to provide their view of the analytical framework that they would use to evaluate these issues. Since the Agencies have taken no action

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HHS study could provide useful information for the Agencies' review of the competitive implications of physician ownership interests in specialty hospitals.

in this area, the Section would also seek clarification as to the Agencies' enforcement policy with respect to single specialty hospitals and the competitive responses of community hospitals.

The Section also encourages the Agencies to address the competitive effect of single specialty hospitals on cross-subsidization (*e.g.,* whether the reduced ability to cross subsidize is an appropriate consideration in the competitive analysis even though the pressure to do so may increase as a result of patient dumping of the indigent or patients whose care is undercompensated) and on quality of care in related markets where cross-subsidization is reduced or eliminated. The Section believes that this is an area where the Agencies could make an important contribution to health care policy by commenting on the competitive effects of Medicare reimbursement that has provided an incentive for specialty hospitals and on EMTALA and other requirements that mandate that certain services be provided by community hospitals (but not single specialty hospitals).

2. Cost Shifting by Hospitals

One of the factors identified in the hearings as a source of financial pressures on hospitals was the substantial proportion of Medicare and Medicaid patients at some hospitals and the prospect or actuality of insufficient reimbursements and recent reductions in reimbursements. Several panelists cited cost-shifting (from Medicare to commercial payors) by hospitals in competitive as well as less competitive markets as a source of upward pressure on negotiated rates with commercial plans. This appears to be an area where additional review of the issues and the available literature would be useful for understanding the implications of cost shifting for competitive effects analysis and the analysis of hospital pricing in recent years. Pressure to raise funds (or endure financial distress) to address lowered reimbursements is also a source of concern raised in the hearings with respect to the financial implications for full service hospitals

from the growth of specialty hospitals. Finally, there is need for additional clarification on how cost-shifting and cross-subsidization would be evaluated in any predatory pricing claims.

3. Merger Analysis

The Section recommends that the Agencies consider using the opportunity of the report on the hearings to address in somewhat greater detail the specifics of health care merger analysis in several areas. There are five areas in which the Section encourages additional guidance.

First, the Agencies could clarify the extent to which they will rely on (and for what purpose) patient origin (flow) data in the empirical assessment of relevant markets, including geographic markets. Several panelists indicated that the data provide insights into market definition, albeit more as a starting point than the sole analytical tool, and that the courts had often relied at least in part on the data. Others appeared to reject the data altogether as a reliable source of information. The Agencies could provide greater transparency by clarifying the ways in which the data will be employed, and identifying any relevant caveat or issues involving the use of such data. In addition, the Agencies could identify whether the use of critical loss and critical elasticity analysis will be used in hospital mergers and provide any additional details on how these will be applied and with what data and information.

Second, participants at the hearings voiced a concern as to whether the Agencies consider the diversion or steering of patients to be effective in disciplining potential price increases by merging hospitals. It would be useful for the Agencies to provide some guidance as to whether and under what circumstance such diversion or steering is considered to be effective in this regard. In particular, the Agencies should address whether and under what circumstances they regard as an effective constraint on such price increases the ability of plans to design benefit

plans or provider compensation to steer patients away from higher cost or lesser quality hospital systems.

Third, market changes have introduced new players into markets in which hospitals are merging. For example, ambulatory surgery centers and specialty hospitals provide competition in some, but not all, of the service lines provided by traditional full service hospitals. The Agencies could provide guidance on how these competitors will be treated in the context of hospital mergers, specifically on such questions as the types of evidence (such as diversion of particular types of patients, pricing levels, etc.) the Agencies will consider or require to show that an ambulatory surgery center provides an effective constraint on potential post-merger price increases.

Fourth, some panelists indicated that hospital merger pricing may be disciplined before and after mergers where hospital Boards included a number of independent directors and functioned with the proper decision rules. It would be useful if the Agencies could indicate in their speeches or in their report on these hearings which, if any, attributes of Board structure and decision-making (such as the number of independent directors, decision rules, capital requirements and other aspects of community boards) would be regarded as imposing price discipline. Finally, to the extent that new learning from the merger retrospectives results in substantial changes to hospital merger analysis (or the relevance of empirical evidence in competitive effects) or in the treatment of efficiencies, this new learning should be conveyed to the broader community in as much detail as possible.

4. Retrospective Merger Reviews

There was a substantial amount of testimony at the hearings on the government's efforts in the hospital merger arena, including a session on post-merger conduct. The Commission's

ongoing retrospective on hospital merger cases was discussed at length in various sessions, in terms of both legal and economic analysis. There was testimony about past hospital merger retrospectives (involving the Butterworth/Blodgett case and the Commission's consent order in Santa Cruz, California) and about the need for additional analysis in other markets.

This is an area in which there is much disagreement about the reasons for and correctness of the courts' decisions not to enjoin hospital mergers. There is also disagreement about the adequacy of previous efforts to analyze post-merger markets and the appropriate approach for the Commission's hospital merger retrospective. The comments, support and criticisms should be weighed carefully by the Commission in its retrospective and by both Agencies when considering future enforcement action.

In particular, the Section believes that post-merger analyses should take into account what the market at issue would have looked like if the merger had not occurred when considering the actual post-merger effects. Factors such as the pre-merger financial strength of hospitals in the market (both those that were parties to the merger and those that were not), the pre-merger prices of the merging hospitals as compared to others in the market, and the mix of services offered by hospitals in the market all could provide a basis for considering what the market would have been like absent the merger. In addition, the Section recommends that the analysis of post-merger effects take into account the difficulties in measuring prices and costs in hospital markets, the effect of uncompensated or undercompensated care on hospital pricing, and how to link changes in prices and costs to the effects of the merger as opposed to other, unrelated factors.

The Commission's guidance in this field could also assess, and, if appropriate, comment on the extent to which contracting practices by hospitals or managed care companies have helped facilitate or deflect exercise of market power by hospitals post-merger.

The Section encourages the Commission to publish its findings from the hospital merger retrospective and to share its views on those findings with the public. The Section also encourages the Agencies to indicate whether these findings will lead to any changes in enforcement policies or analytical principles**.** It would be useful for the Commission to identify the results of their inquiry into the effects of the consolidation.

Finally, to the extent the merger retrospective provides the Commission with additional insight into the appropriate economic framework for market definition, analysis of unilateral and coordinated effects, entry, efficiencies achieved from the merger, and the key empirical evidence that is relevant to the analysis, these factors should be addressed in as much substantive detail as possible in any ensuing report.

5. "Virtual Mergers" and Other Forms of Structural Integration Among Providers

In the Section's Workshop Comments, we noted that in recent years hospitals have formed a variety of affiliations, networks, joint ventures, partnerships or new corporations that result in joint marketing of hospital services without a complete merger of the hospitals involved. These arrangements sometimes have been described as "virtual mergers." While there is some reference to hospital mergers in the Policy Statements*,* the subject of virtual mergers or joint operating agreements among hospitals is not discussed in the Policy Statements. Similarly, physicians have integrated into groups that have more indicia of integration than the traditional independent practice association ("IPA"), and through which the physicians provide all their services, but which still may fall short of a complete merger of their practices. Some of these

groups are referred to as "clinics without walls," or "groups without walls," to represent the fact that the physicians forming these entities often remain in their original locations, while providing or purporting to provide their services through a new, single entity.

Statements 8 and 9 of the Policy Statements discuss integration among networks of providers at great length, but their focus is on integration among otherwise separate and competing providers who enter into network arrangements for the purpose of contracting with third party payors. The statements observe that pricing activities among providers who accept and share substantial financial risk, or who integrate "clinically," may be viewed under the rule of reason rather than the *per se* rule. The Statements do not address "virtual mergers" of either hospitals or physicians. Two recent court decisions cast some light on these issues. In the first, *New York v. Saint Francis Hospital*, 94 F. Supp. 2d 399 (S.D.N.Y. 2000), a court held that two hospital systems that had formed a joint venture to operate certain services had engaged in a *per se* illegal violation of Section 1. In *St. Francis*, the hospitals did not claim to be protected from an attack under Section 1 under the *Copperweld* doctrine. *See Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752 (1984). Instead, the hospitals argued (unsuccessfully) that they had formed a legitimate joint venture that should be judged under the rule of reason, rather than the *per se* rule. More recently, in *HealthAmerica Pennsylvania v. Susquehanna Health System*, 278 F. Supp. 2d 423 (M.D. Pa. 2003), a court found that the *Copperweld* doctrine does apply to two hospital systems that combined their hospitals but preserved the separate parent entities of each of the two combined systems.

It is our understanding that the Agencies have investigated some joint hospital arrangements, or "virtual mergers," without taking any enforcement actions, and that the Agencies have investigated physician groups that involve more integration than seen in the

typical IPA. A recent Commission enforcement action in Yakima, Washington, [3] for example, appears to have involved an entity that could be characterized as a clinic without walls and that may have had more indicia of integration than were present in most of the physician networks that typically have been the subject of governmental enforcement activity.[4] The Commission action ended in a consent order, however. Consequently, the allegations of integration were not adjudicated, nor even discussed, by the Commission and the matter provides little guidance for practitioners.[5]

In the Section's Workshop Comments submitted last Fall we noted that, among other things, an exploration of the Agencies' position and an explication of their views on the application of the *Copperweld* doctrine in the context of so-called "integrated delivery systems" could provide very helpful guidance to practitioners. We suggested that guidance could address such issues as the factors that bear upon single-entity analysis, including the importance of formal corporate structure among the members of the network as distinct from substantive considerations inherent in the notion of a "unity of interest."

The hearings (on April 10 and September 25) addressed some of these issues. During the April 10, session, for example, one panelist noted that an important issue is presented by joint

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[3] *In the Matter of Surgical Specialists of Yakima, P.L.L.C.; Cascade Surgical Partners, Inc., P.S.; and Yakima Surgical Associates, Inc., P.S.,* Docket No. C-4101 (November 18, 2003) (available at www.ftc.gov/os/caselist/0210242.htm).

[4] According to pleadings in a separate class action, the physicians formed a limited liability company that maintained all revenues in a single bank account, employed all clerical, clinical and administrative staff, adopted a common compliance program, lowered the cost of malpractice premiums for its members, entered into favorable purchasing arrangements with vendors, offered health care and other benefits to all employees and brought clinical improvements in trauma services and for breast cancer patients. *See* Answer to Complaint in *Hinman v. Yakima Surgical Associates, et al.,* No. CY-02-3119-FVS (E.D. Wa.) (filed January 13, 2003); Defendants' Memorandum in Opposition to Plaintiffs' Motion for Class Certification (and supporting affidavits) (filed June 6, 2003).

[5] *In the Matter of Surgical Specialists of Yakima, P.L.L.C.; Cascade Surgical Partners, Inc., P.S.; and Yakima Surgical Associates, Inc., P.S.,* Docket No. C-4104 (November 18, 2003) available at www.ftc.gov/os/caselist/0210242.htm). A settlement of the class action was approved by the Court on December 15, 2003; hence the issues discussed in the text were not adjudicated in that litigation either.

operating agreements that result in joint pricing while achieving cost savings. One speaker noted that a virtual merger differs from an outright merger in that the parties involved usually retain a degree of operational and financial independence that parties in an outright merger do not. The comment also was made that in some cases virtual mergers can achieve greater efficiencies than actual mergers.

The Section recommends that the Agencies consider providing guidance in this area. The Policy Statements do not address the issue, and the one speech from an enforcement official on the matter, which was very helpful when it was made, is now five years old and predated *Susquehanna*.[6]

6. Clinical Integration

In the Section's Workshop Comments, it indicated that the topic of "clinical integration" for physician network joint ventures would benefit from further clarification and amplification. The hearings further underscored the need for more guidance regarding clinical integration.

The Policy Statements first mentioned clinical integration as an acceptable integration method for physician network joint ventures in 1996. The Policy Statements contained a description of the desirable attributes of a clinical integration program and two hypothetical examples of satisfactory clinical integration. However, since 1996, the Agencies have issued only one advisory opinion in February 2002 analyzing the proposed clinical integration program of MedSouth, Inc., a physician IPA located in Denver, Colorado, area.

[6] Mark J. Botti, *Virtual Mergers of Hospitals: When Does the Per se Rule Apply?*, in ANTITRUST AND HEALTH CARE: INSIGHTS INTO ANALYSIS AND ENFORCEMENT, 181 (ABA 1999). Mr. Botti, who was with the Health Care Task Force at the Antitrust Division at the time of the speech, commented on a transaction amounting to a "virtual merger" that was proposed by hospitals on Long Island. Ultimately the hospitals determined to forego a "virtual" merger, and engaged in a full merger – which was itself challenged (unsuccessfully) by the Department under Section 7 of the Clayton Act. *United States v. Long Island Jewish Medical Center*, 983 F. Supp. 121 (E.D.N.Y 1997).

The clinical integration topic most recently was addressed in a July 2003 Complaint issued by the FTC against California Pacific Medical Group, d/b/a/ Brown & Toland Medical Group. In that Complaint, the Commission indicated in brief factual allegations that the physicians in the Brown & Toland network did not monitor practice patterns and quality of care, and did not enforce utilization standards regarding services provided by its network for the fee-for-service lines of business in which the respondent allegedly restrained competition.

Thus, in the seven years since the Policy Statements were issued, the main specific sources of legal guidance available to health care providers interested in developing clinical integration programs are the hypothetical examples contained in the Policy Statements, the MedSouth staff advisory letter and the brief statement in the Brown & Toland Complaint which mentions the same factors as the Policy Statements. While the Agencies have provided a substantial amount of guidance for physician network joint ventures interested in utilizing financial risk sharing methods through advisory opinions, business review letters and enforcement actions, there is a limited amount of specific guidance on the issue of clinical integration. While the MedSouth advisory letter suggests a very rigorous and fairly burdensome approach for establishing a clinical integration program, it is possible that less rigorous and less burdensome programs can be established that still satisfy the standards set forth in the Policy Statements and are consistent with the ancillary restraints doctrine in case law. As a result, the Section suggests that it would be beneficial for the Agencies to provide more specific guidance on the types of clinical integration programs that would or would not be acceptable. Such guidance could be provided in the form of revisions to the Policy Statements, speeches, or, if requested, business review letters, or advisory opinions. In particular, it would be beneficial for the Agencies to describe the types of clinical integration programs that may have resulted in

Agency decisions not to challenge certain networks in the past and the basis on which the Agency had concluded that common contracting and pricing was necessarily related to the accomplishment of the venture. Without revealing the specifics of any investigation, the Agencies could provide a service to the health care community in sharing such observations on the types of clinical integration that appear to have addressed the issues of concern to the Agencies.[7]

For example, amplification of the circumstances in which a combination of physicians was deemed to have been sufficient to create a "new product" would prove very useful. *See* Policy Statements, n. 36 & 46. Additional detail on the means by which it can be demonstrated that agreements on price are reasonably related to the achievement of efficiencies would also prove useful for assisting practitioners to determine *ex ante* when the rule of reason is likely to apply. Arguably, attempting to determine when agreements on price are "reasonably related" to achieving efficiencies is one of the murkiest areas of antitrust analysis. Therefore, further discussions by the Agencies on this topic, perhaps with examples of hypotheticals, would serve to enlighten the provider community. Along these same lines, a discussion addressing clinical integration in the context of physician/hospital relationships where a single hospital provides the opportunity for clinical integration among its physician staff would be helpful.

In sum, the Section believes it would be highly beneficial if the Agencies engaged in a more robust discussion and exploration of how and when clinical integration can qualify for a rule-of-reason analysis in the context of joint price negotiation.

[7] The Statement prepared by the FTC in Royal Caribbean Cruises, Ltd., FTC File No. 0210041 (2002) was particularly helpful in this regard.

7. Consideration of More Aggressive Remedies for Egregious Conduct that has Repeatedly Been the Subject of Enforcement Actions

The Commission and the Antitrust Division have brought numerous enforcement actions against health care providers and organizations of health care providers for alleged collusion on price as regards third party payor programs and for participation in anticompetitive concerted refusals to deal with managed care programs. Absent litigated hearing records, there are, of course, no findings that document the allegations that have been made in these enforcement actions. In addition, some observers might have concerns whether the allegations made or remedies imposed in certain of the actions have been merited. On balance, though, if there is merit to the allegations made in the cases that have been brought, it would appear that this conduct has continued to occur in some health care markets around the country despite a record of enforcement in similar cases by the Commission and the Antitrust Division dating back over 20 years. The hearing record included considerable discussion of the limited deterrent effect that past agency enforcement actions have apparently had in this regard, and the relative paucity of private treble damage actions.

The Agencies and the courts have a variety of enforcement tools and potential remedies available to them. The Department of Justice, of course, has the authority to bring criminal charges. The Commission has also successfully sought various forms of monetary, disgorgement or restitution relief in a limited number of unfair method of competition cases, particularly in recent years, and has sought guidance from the public on the circumstances when it might seek to exercise that type of authority. It would be valuable for the Agencies to apprise the public, the parties active in the health care industry, and the bar on circumstances under which they would consider more aggressive enforcement or remedial strategies where egregious violations are

occurring, with possible harm to patients, customers or the general public from types of conduct that have been the subject of repeated enforcement actions over the years.

8. Quality Considerations in Antitrust Analysis

Providers often complain that collaborative conduct to improve quality is misunderstood and subject to unjustified antitrust risk. As one law review article put it, "Courts possess a limited grasp of what constitutes health care quality and how competition can be designed to further it."[8] Commendably, the Agencies devoted several sessions of the hearings to quality issues.

As the Section noted in the Section's Workshop Comments submitted last year, if competitive forces and antitrust policy are to contribute to better quality in health care, participants in health care markets, both providers and payors, need to begin first by understanding better what is meant by "quality health care." The hearings explored the questions of what quality is, and whether (and how) it can be measured, with valuable input from individuals with varying perspectives. At the session on "Quality and Consumer Information: Physicians," for example, one speaker noted that measurements of physician quality can be disease specific, can be standardized across large delivery systems and regions and can be applied to all physicians, while results can be measured and monitored quickly. Evidence-based quality control measures exist, such as patient care guidelines for best practices. These guidelines are becoming the standard methodology with which to assess clinical decisions, document quality, and determine appropriate care.

At a related session on "Quality and Consumer Information: Hospitals," the discussion focused on what should be reported about hospital quality, how it should be reported, and

[8] Peter J. Hammer & William M. Sage, *Antitrust, Health Care Quality, and the Courts*, 102 Colum. L. Rev. 545, 637 (2002).

whether hospital report cards are effective. One panelist discussed different types of report cards at length and noted that some recent studies suggest that outcome report cards may be effective in improving health care actually delivered to patients. Yet, such report cards may have a negligible effect on consumers' decisions in choosing hospitals. One problem with evaluating quality in procedures performed is that this does not address the important underlying issue of whether a procedure was necessary in the first place. As the Section noted last year, quality problems occur not just when medical resources are misused or underused, but when resources are overused as well. Overuse of resources should be of particular concern to policy makers in that improving quality by reducing overuse should lead, not just to improved outcomes, but to lower health care expenditures as well.

Unfortunately, speakers at the hearings spent comparatively little time addressing how quality considerations should factor into the thinking of the courts and the Agencies. The Agencies could help alleviate concern among the members of the health care industry that quality is ignored in the enforcement matrix, and provide more guidance by emphasizing that the antitrust laws are not an impediment to improving quality in health care, and by discussing ways in which quality considerations have factored into actual enforcement decisions. For example, last year, Chairman Muris commented that the FTC had "recently closed an investigation in which physician collaboration resulted in a substantial degree of market concentration because the parties demonstrated that considerable efficiencies resulted, notably dramatic improvements in the quality of care."[9] It would be useful if the Commission and the DOJ were to draw on this and other experiences to provide concrete examples of how quality is factored into the competitive matrix at both Agencies.

[9] "Everything Old is New Again: Health Care and Competition in the 21st Century," November 7, 2002, available at www.ftc.gov/speeches/muris/murishealthcarespeech0211.pdf.

Finally, in the Section's Workshop Comments, the Section commended the thought and attention that the Agencies have devoted to payment mechanisms in the context of concerns about price competition. We noted, however, that more guidance may be needed to help address how antitrust enforcement may take into account the way those payment mechanisms could affect the market, in terms of cost, efficiency, quality and innovation. In addition, Agency guidance could be helpful in addressing the perception held by some that capitation has a "preferred status" in antitrust analysis. *See* Policy Statement Nos. 8 & 9.

9. Group Purchasing

The testimony at the hearings focused on certain contracting practices used by group purchasing organizations -- including sole source contracting, commitment requirements, and bundling. The witnesses at the hearings offered differing perspectives on whether these practices are likely to have anticompetitive effects. On the one hand, some medical device manufacturers reported that these practices prevent them from selling their innovative products to hospitals, thereby erecting barriers to entry and restricting competition. On the other hand, the group purchasing organizations stated that these practices create efficiencies and help them to achieve better pricing. In the long run, they assert, this keeps health care costs down.

Statement 7 of the Policy Statements addresses group purchasing by health care providers. It sets forth safety zones for group purchasing arrangements that the Agencies did not believe would lead to anticompetitive effects. These safety zones are based on the structure of the market in which the purchasers operate, and do not specifically address the contracting practices at issue in the hearings. The Section recommends that the Agencies review Statement 7 with these contracting practices in mind and consider whether to offer additional guidance on the effects of these practices on competition among medical suppliers as well as on competition among health care providers.

Another issue that was raised at the hearings was the question whether the large group purchasing organizations have monopsony power, and whether that contributes to anticompetitive effects (if any) in any market(s) for medical suppliers. Statement 7 provides a market share threshold below which a group purchasing organization will be presumed not to have monopsony power. The Section suggests that the Agencies consider providing additional guidance specifically addressing the allegations that some group purchasing organizations pose a danger to competition and do not serve consumers' interest.

C. Provider/ Payor Issues

1. Hospital/Payor Contracting

The contracting dynamics and environment between hospitals and health care plans have changed in many markets in recent years, largely due to the pervasive backlash against managed care, consumer demand for choice among hospitals, and according to some, the increasing market strength of hospitals. Testimony at the hearings indicated that on the hospital side, hospitals have been utilizing a number of new contract practices such as (1) requiring that health care plans contract with all of the hospitals in a hospital system, (2) requiring that health plans also contract with certain physician groups affiliated with a hospital, (3) requiring contracts with a hospital's ambulatory surgery center as a condition of contracting with that hospital, (4) requiring that all hospitals in a system be placed in the highest benefit tier, and (5) insisting on joint price negotiations by hospitals that claim to affiliate through clinical integration or other integration short of merger. On the payor side, some witnesses testified that a number of health care plans have been requiring that hospitals enter into participating provider agreements for all of the products offered by those plans.

These contracting practices, by both hospitals and payors, may be based upon legitimate business considerations and therefore may be procompetitive. In other cases, however, each of these contracting practices has the potential to produce anticompetitive effects. For example, the system-wide contract requirement employed by some hospital systems may enable those systems to realize negotiating efficiencies and spread their fixed costs over a larger base. On the other hand, a system-wide contract requirement may result in higher rates being paid by health care plans to hospitals and less competition among health plans to the extent they end up having virtually identical provider networks. Under these circumstances, payors will need to find alternative ways to differentiate themselves and new bargaining techniques to achieve reduced prices. Where this can be accomplished, anticompetitive consequences would likely be avoided. Some commentators suggested during the hearings that the use of a system-wide contracting requirement may lead to hospitals being able to extract higher than competitive rates from health care plans, but further analysis is warranted to determine whether health care plans can counteract this by steering patients to other hospitals when they are available. Accordingly, in analyzing system-wide contracting by hospital systems, it will be important to examine whether health care plans actually have the ability to steer patients away from such systems through incentive arrangements with providers, tiered benefit designs or other case management techniques, or whether hospital systems may be able to counteract such practices through contractual language forestalling these measures.

Unfortunately, there has been very little economic analysis conducted or economic literature published on the effects on hospital or payor contracting practices. Furthermore, there also has not been a great deal of explicit government enforcement activity in this area (other than that which has arisen in the context of mergers). The Section suggests that hospital/payor

contracting practices should be subject to careful antitrust review by federal and state enforcement officials. The Section fully supports balanced enforcement of the antitrust laws in the health care industry, whether reviewing the contracting practices of hospitals or payors. Hospital/payor contracting practices should be subject to government scrutiny in an effort to prevent anticompetitive activities by either hospitals or payors. This scrutiny should be sensitive to changing market conditions and developments, such as increasing concentration on the hospital or payor side and changes in the relative market strength of hospitals or payors in a particular relevant market.

2. Most Favored Nation Clauses

"Most favored nation" ("MFN") clauses in contracts between managed care payors or networks and individual health care providers were a topic of discussion at the hearings and have also been a focus of significant antitrust enforcement activity.[10]

Enforcement actions reflect concern that where a provider-sponsored network requires its participating providers to execute most favored nation commitments, these commitments may be the product of a horizontal conspiracy, which may foster collusive pricing by creating an effective floor on prices charged by the providers to all payors. Also, where a third party payor imposes MFN requirements on its participating providers in a vertical arrangement, an expressed enforcement concern is that in some market circumstances prices to other payors may be kept up and barriers to entry raised. Thus, the Antitrust Division website explains that "[w]hile not all MFNs violate the antitrust laws, they can, under certain market conditions, discourage provider discounting, deter innovation, and reduce meaningful consumer choices in health plans, either by

[10] *See, e.g., RxCare of Tennessee, Inc.* , 121 F.T.C. 762 (1996) (consent order); *United States v. Medical Mutual of Ohio*, Civil Action No. 1:98:CV-2172 (N.D.Ohio Jan. 29, 1999); *U.S. v. Delta Dental of Rhode Island*, 943 F. Supp. 172 (D.R.I. 1996) (denial of motion to dismiss); 1997-2 Trade Cas. (CCH) ¶71,860 (D.R.I. July 2, 1997) (consent decree); *U.S. v. Vision Service Plan*, 1996-1 Trade Cas. (CCH) ¶ 71,404

facilitating collusive pricing among competing providers or by discouraging providers from offering lower rates or more cost-effective care to rival plans."

In contrast, it seems clear, at the safe end of the spectrum, that an MFN clause imposed vertically by a payor with a very limited market share would not normally raise material antitrust risks. It also appears that inclusion of MFN terms in a payor's contracts with only a small portion of its participating providers in a market area would not normally raise antitrust problems.

The Section encourages the Agencies to consider issuing a new policy statement or provide other guidance clarifying the MFN characteristics and other market facts that would bear on their assessment of MFNs in situations not fully parallel to those already addressed by enforcement actions.

D. Payor Issues

1. Empirical Analysis of Monopsony Power By Payors

The existence or exercise of monopsony power by health care payors is not specifically addressed in the Policy Statements.[11] The Agencies also have not devoted a substantial amount of attention to monopsony power issues, except in the context of a few health care plan mergers, and there is a substantial divergence of opinion as to whether health care plans today actually have monopsony power. Moreover, many courts have failed to appreciate the differences between seller market power and buyer market power. The discussion of these factors during the hearings underscored the need for further analysis of and guidance on the issue of monopsony power.

(D.D.C. 1996). *See also U.S. v. Oregon Dental Service*, 1995-2 Trade Cas. (CCH) ¶ 71,062 (N.D. Ca. 1995); *U.S. v. Delta Dental Plan of Arizona, Inc.*, 1995-1 Trade Cas. (CCH) ¶ 71, 048 (D. Ariz. 1995).

[11] The Policy Statements do address group purchasing by health care providers and provide a safety zone in Statement 7.

The hearings also highlighted the difficulties that exist when attempting to evaluate and measure monopsony power among health care purchasers. For example, it may be difficult to determine whether low prices paid by managed care organizations could be the result of monopsony power or instead merely reflect some ability to take advantage of competition among health care providers or otherwise purchase efficiently. Likewise, there was debate among the panelists about whether monopsony power, if it does exist, is a short-run or long-run issue, how to determine whether the rate of reimbursement to hospitals and/or physicians is competitive, and how to define the geographic and product market, including such issues as whether the provision of services to Medicare patients should be considered in analyzing allegations of market power by health care plans. Furthermore, the interplay of provider and insurer market power has to be taken into consideration in analyzing monopsony power (and potentially as well when considering provider market power issues).

Some government officials and private parties have been operating under the assumption that monopsony power actually exists in health care markets today and that it has been exercised to the detriment of consumers. There is limited published empirical research on the actual, as opposed to theoretical, effects of monopsony power by health care purchasers.[12] Therefore, the Section suggests that empirical studies should be conducted to test this assumption, and the findings from these studies should be used to inform and shape government enforcement policy. In particular, the Agencies may wish to conduct empirical studies to set out more clearly the conditions that facilitate monopsony power and its exercise and to examine the implications of monopsony power on pricing relative to competitive levels. Furthermore, the Agencies could conduct empirical studies to determine the effect of the exercise of monopsony power in health

[12] *See* William J. Lynk, *Some Basics About Most Favored Nation Contracts In Health Care Markets*, THE ANTITRUST BULLETIN 491, 493-4 (2000).

care markets on consumers. If the Agencies choose to conduct such studies, they may wish to consider such factors as the appropriate measures of price in these markets, how to determine competitive pricing levels, and how to compare the different products and services offered by different firms in these markets. Based on the results of these empirical studies, more specific guidance on the Agencies' approach to monopsony power issues, whether in the form of revisions to the Policy Statements, enforcement actions, business review letters, advisory opinions or speeches, would be beneficial.

2. Recommendation that Agencies Work with the NAIC to Update its Model Insurance Holding Company Act's Competition Review Standards

The National Association of Insurance Commissioners ("NAIC") is an association of state and other governmental officials with key authority for regulating the activities of insurance companies and other firms in insurance-related fields. It develops model acts and model regulations which are often relied upon by state legislatures and state insurance departments in the development of their own laws and regulations. Its member state officials have broad-based authority to regulate the operations and transactions of insurance companies and insurance-related entities, including health insurers and HMOs. The NAIC's Model Insurance Holding Company Act includes provisions calling for insurance commissioner review of the competitive effect of acquisitions of insurers and other entities within the reach of the model law. The law has been adopted in whole or in part by most states. The law gives state insurance departments a valuable tool in helping to protect competition in health care insurance markets. However, as was discussed at the hearings, the Model Act codifies presumptions of anticompetitive effect that are out of line with modern federal antitrust case law and current enforcement guidelines.

The Model Insurance Holding Company Act establishes a market share test for the combining parties to determine whether the shares constitute prima facie evidence of an

anticompetitive effect, so as to warrant disapproval of a proposed acquisition absent affirmative evidence to the contrary. The tests are reminiscent of antitrust standards that were posited in the 1960s, but which have not had widespread adherence since then. Specifically, for example, under the Model Act, a merger of two insurers each with a 4% market share in a "highly concentrated" market where four other firms collectively had 75% or more of the market would be presumptively illegal even though after the merger, by way of example, there would still be four insurers each with a 19% market share, one insurer with a combined share of 8% and four firms each with a 4% share. In contrast, under the Agencies' current *Merger Guidelines*, the same transaction would be viewed as "unlikely to have adverse competitive consequences and ordinarily [would] require no further analysis."

The prima facie standards under the NAIC Model Act in markets that are ***not*** highly concentrated are even more of a departure from current antitrust standards. For example, under the NAIC Model Act, a merger would be prima facie anticompetitive if the acquiring firm and acquired firm have the following shares of a market, respectively:

5% and 5% or more

10% and 4% or more

15% and 3% or more

19% and 1% or more

Thus, any merger in a market where there were twenty insurers each with a 5% market share would be presumptively illegal. In contrast, the *Merger Guidelines* would characterize such a market as "unconcentrated" and according to the *Merger Guidelines*, "mergers resulting in unconcentrated markets are unlikely to have adverse competitive effects and ordinarily require no further analysis."

We encourage the Agencies to work with the NAIC on a collaborative basis to improve mutual understanding, the potential for cooperation and consistency in merger enforcement. Such interaction could benefit both NAIC and the Agencies. One such initiative could be for the Agencies to explore with NAIC whether an update to the Model Insurance Holding Company Act competition review standards would be in order. One possibility would be for the Model Act to avoid specific reference to particular market shares, but to reference thresholds in the Merger Guidelines as a point of reference.

III. ROLE OF THE AGENCIES

A. DOJ's Role Beyond the FTC's Jurisdiction

The Commission and the Department of Justice share responsibility for enforcement of key federal laws intended to protect competition – the Department enforcing the Sherman and Clayton Acts, and the Commission enforcing the Clayton and FTC Acts. Although the Commission has recently generated more case activity in the health arena than the Department, both agencies have essential roles. Much of the economic activity in health care services and health care financing markets is conducted by nonprofit organizations. Where their conduct does not lie within the reach of the Clayton Act, many of these non-profit organizations likely fall outside what is generally viewed as being the jurisdictional reach of the FTC Act. This contrasts with merger law enforcement, where the Commission has maintained its authority to act against anticompetitive mergers of non-profit hospitals under the terms of the Clayton Act.

Section 5 of the FTC Act empowers the Commission to prevent unfair methods of competition and unfair or deceptive acts or practices by persons, partnerships or corporations. Under Section 4 of the FTC Act, "corporation" shall be deemed to include any company, trust or association, incorporated or unincorporated, which is "organized to carry on business for its own

profit or that of its members". This language has been construed to exempt truly eleemosynary charitable organizations from the FTC Act's reach, while permitting the Commission to enforce the FTC Act against certain non-profit entities, such as trade and professional associations that operate in substantial measure to serve the pecuniary interests of their members. It is not within the scope of this comment to address the full scope of the Commission's authority or potential authority under the FTC Act. Rather, the record of the hearings indicates that there is a broad range of competition and antitrust issues that arise in the conduct of business by health care industry entities. Some of these organizations may, by virtue of their non-profit charitable status, fall outside the Commission's law enforcement authority. Challenging monopolization and agreements that unreasonably restrain trade in health care to the detriment of the public is a legitimate focus of federal antitrust enforcement, regardless of the actor's profit or non-profit status. Where one of the Agencies lacks enforcement authority by virtue of its enabling legislation, it is all the more important that the other be vigilant and visible. We encourage the DOJ, therefore, to be active in its antitrust enforcement, to the extent appropriate under the facts of any individual case, in any sectors of the industry, such as can be the case for some non-profit entities, where the Commission must, under prevailing law, stand back.

B. Urge Agencies to Remain Proactive in Advising State Agencies and Legislatures of Competitive Effects of Proposed Actions in Health Care Field

The Agencies have long played a valuable role in providing guidance and perspective on the competitive and consumer impact of proposed legislative and regulatory actions in health care and other fields. This is a valuable role that the Agencies can play, taking advantage not only of their formal role as protectors of consumers and competition, but also of the specific industry expertise that they have developed. Antitrust principles and protection of competition need not, of course, be the appropriate benchmarks in all instances for sound legislation and

regulation at the state and local level. Other considerations necessarily and appropriately can enter into decision-making. It can be very valuable, though, for the Agencies to provide their particular perspective and insights to state legislative and regulatory bodies considering actions that may have significant competition and consumer effects. We urge the Agencies to continue to be proactive in bringing an informed competition and consumer perspective to state agencies and legislatures. This can be particularly helpful where proposed legislation or administrative action threatens competition by other competitive and cost-effective providers, like allied health providers, or where the impact of a proposed action or policy on competition by innovative, smaller or new competitors and on resultant consumer choice may not have been carefully considered. This comment is not made in derogation of the Agencies' consideration of direct law enforcement action where conduct is properly within their reach.

C. Encourage Proactive Role for Agencies in Providing Competition and Consumer Perspective to other Federal Agencies Considering Actions Affecting Health Care Consumers and Patients and Competition in Health Care Markets

Through Medicare, Department of Defense TriCare, the Department of Veteran Affairs, Medicaid dollars, and other programs, the federal government is the largest payor for health care services and products in the country. The laws, regulations and policies under these programs have enormous impact on competition and consumers. In addition, other federal legislative and regulatory enactments also significantly affect the ways in which health care providers, payors and product manufacturers must behave and may compete in the market, as was discussed during the hearings. These requirements range from EMTALA requirements for emergency care and their potentially disparate impact on general acute care hospitals in contrast to single specialty hospitals, to laws governing the availability of health insurance for small employers, and laws affecting the availability of prescription drugs in the marketplace. Federal programs and

requirements often run parallel to bedrock antitrust principles of competition and consumer choice, and deal with perceived instances of market failure. In other instances, government rules or proposals appear to be in tension with market or competition-based activity, or else advance governmental objectives in ways that unnecessarily constrain or limit what would appear to be legitimate and pro-consumer forms of competition.

The Agencies have filed comments with other federal agencies on proposed actions that could have significant impact on health care consumers and patients. We encourage the Agencies to strengthen this activity, and to become more active, to the extent budgetary considerations permit, in providing competition and consumer perspective to other federal agencies considering actions in the health field. The scope of the "safe harbors" under the federal health care program anti-kickback law, 42 U.S.C. § 1320a-7b(b), the regulations adopted under the "Stark" law, 42 U.S.C. §1395nn, differential application of some financial or patient responsibilities to some types of health care providers but not others, and the imposition of limitations on hospitals' ability to selectively reduce copayments for outpatient services by contractual agreement with managed care organizations are examples of federal actions that may have significant competitive effects. There are many others. In some instances, moreover, other agencies are seeking to import notions of "fair competition" into their own regulatory standards or enforcement discretion. Given the impact of federal regulatory and policy decisions in these and many other areas, the need for informed decision-making, and the benefits of the Agencies' particular antitrust expertise and perspective can be particularly important.

IV. CONCLUSION

The Section expresses its appreciation to the Agencies for their in-depth review of the health care industry and their consideration of topics of importance to the Section and its members.

The Section encourages the Agencies to provide additional guidance through speeches, informal advisory letters, revision and expansion of the Policy Statements and their report on the hearings on a number of topics outlined in these comments that are of interest to hospitals, physicians, payors and the public. The Section suggests that a bibliography on recent published and unpublished literature cited or provided at the hearings would also be of great assistance to the private bar and the public, and the Section would be willing to assist in those efforts.

The Section believes that it is important for the Agencies to continue to be proactive in competitive issues in health care policy at the state level and to be more proactive in working with other agencies at the federal level involved with health care with respect to issues affecting competition in the health care industry. The Section also encourages the DOJ to be active in its antitrust enforcement, to the extent appropriate under the facts of any individual case, in those sectors of the health care industry that are beyond the FTC's jurisdiction.

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